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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,674	10/18/2004	Yasuhito Yamamoto	0283-0202PUS1	6392
2292 7590 06/25/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 EALLS CHURCH VA 22040 0747			EXAMINER	
			OH, TAYLOR V	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1625	, <del>, , , , , , , , , , , , , , , , , , </del>
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			NOTIFICATION DATE	DELIVERY MODE
			06/25/2007	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

	Application No.	Applicant(s)			
	10/511,674	YAMAMOTO ET AL.			
Office Action Summary	Examiner	Art Unit			
·	Taylor Victor Oh	1625			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory peri  - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b).  Status	DATE OF THIS COMMUNI 1.136(a). In no event, however, may a od will apply and will expire SIX (6) MOR tute, cause the application to become Al	CATION. reply be timely filed  NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).			
	0.0-4-60004				
·— ·	Responsive to communication(s) filed on <u>18 October 2004</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.				
,	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ☐ Claim(s) 1-20 is/are pending in the application 4a) Of the above claim(s) is/are with definition 5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-20 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and	lrawn from consideration.				
Application Papers					
9) The specification is objected to by the Exam 10) The drawing(s) filed on is/are: a) a Applicant may not request that any objection to t Replacement drawing sheet(s) including the corr 11) The oath or declaration is objected to by the	nccepted or b) objected to he drawing(s) be held in abeya rection is required if the drawing	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a)  All b)  Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date 10/18/04.</li> </ol>	Paper No	Summary (PTO-413) s)/Mail Date Informal Patent Application			

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The Status of Claims

Claims 1-20 are pending.

Claims 1-20 have been rejected.

### **DETAILED ACTION**

1. Claims 1-20 are under consideration in the application.

### **Priority**

2. It is noted that this application is a 371 of PCT/JP03/04962 (04/18/2003), which has foreign priority documents, Japan 2002-117285 (04/19/2002) and Japan 2002-117286 (04/19/2002).

#### **Drawings**

3. None.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-2,4,6,12-13, 15, and 17, the phrase "substituted" is recited. This expression is vague and indefinite because in the absence of the specific moieties intended to effectuate modification by the "substitution" or attachment to the chemical core claimed, the term "substituted" renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed. Therefore, an appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protease, esterase, and lipase as a hydrolyase, does not reasonably provide enablement for all kinds of hydrolases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all kinds of hydrolases unrelated to the invention commensurate in scope with these claims.

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In biochemistry, a **hydrolase** is an enzyme that catalyzes the hydrolysis of a chemical bond. For example, an enzyme that catalyzed the following reaction is a hydrolase:

$$A-B + H_2O \rightarrow A-OH + B-H$$

Furthermore, the specification has not described how all kinds of hydrolases are capable of hydrolyzing the claimed compounds; in addition, hydrolases can be further classified into several subclasses depending on the bonds they act on:

- EC 3.1: ester bonds (esterases: nucleases, phosphodiesterases, lipase, phosphatase)
- EC 3.2: sugars (glycosylases/DNA glycosylases, glycoside hydrolase)
- EC 3.3: ether bonds
- EC 3.4: peptide bonds (Proteases/peptidases)
- EC 3.5; carbon-nitrogen bonds, other than peptide bonds
- EC 3.6: acid anhydrides (acid anhydride hydrolases, including helicases and GTPase)
- EC 3.7: carbon-carbon bonds
- EC 3.8: halide bonds
- EC 3.9: phosphorus-nitrogen bonds
- EC 3.10: sulfur-nitrogen bonds
- EC 3.11: carbon-phosphorus bonds
- EC 3.12: sulfur-sulfur bonds
- EC 3.13: carbon-sulfur bonds

From this information, it becomes clear that the special type of the bond needs a particular kind of hydrolase in the reaction process.

Therefore, it seems unrealistic that any kinds of hydrolyses would not work for the claimed generic reaction conditions so as to produce the desired product. Therefore, an appropriate correction is required.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Taylor Victor Oh, MSD,LAC

Primary Examiner

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··· 6/18/07